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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/963,959	09/25/2001	Rachel E. Meyers	10448-095001	1570

7590

08/26/2002

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EXAMINER

SAKELARIS, SALLY A

ART UNIT

PAPER NUMBER

1634

DATE MAILED: 08/26/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/963,959

Applicant(s)

MEYERS, RACHEL E.

Examiner

Sally A Sakelaris

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 July 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 8 and 13 is/are pending in the application.
- 4a) Of the above claim(s) 5-7, 9-12 and 14-21 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-4 and 8 is/are allowed.
- 6) ☒ Claim(s) 13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I, claims 1-4, 8, and 13, in Paper No. 7 is acknowledged.

Specification

The disclosure is objected to because of the following informalities: multiple omissions are included in the repeated phrase of the "plasmid deposited with ATCC accession number ____." Applicant is required to remove the empty spaces from the text of the specification. MPEP § 2421.02. Applicant is reminded however, that new matter cannot be added to the specification.

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code(Pg. 10, for example). Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Appropriate correction is required.

Priority

Acknowledgement of priority to the provisional application drawn to this same subject matter has been made. The filing date of the instant claims is deemed to be the filing date of the present application 09/963959 on 09/25/2001.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Duhl(WO97/46680) in view of Ahern(The Scientist, 1995).

Duhl teaches a nucleic acid probe or primer that selectively hybridizes to the isolated nucleic acid molecule comprising the nucleotide sequence of SEQ ID NO: 1, of the present application(WO97/46680, pg 42 SEQ ID NO: 1). This selective hybridization is possible as a result of the nucleic acid of Duhl sharing 99.8% identity with nucleotides 3416-5426 of instant SEQ ID NO:1(Please refer to sequence search page 9, result 5 for alignment).

Duhl does not explicitly teach the inclusion of the aforementioned nucleic acids into kits with instructions.

However, Ahern teaches combining known reagents into kits that are sold as a product. Ahern teaches, with respect to various methods and products, that the compilation of solutions and components used in methods adds a great deal of efficiency to a piecemeal lab protocol.

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Duhl so as to have included all of its reagents in a kit since the expected benefit exists of "buying pre-made reagents and kits are convenient and save time"(Pg.4, Ahern). Ahern also teaches that

“rather than browsing through catalogs and buying individual chemicals from one or several suppliers, investigators can instead purchase a kit that supplies all of the necessary reagents”(The Scientist, 1995).

Furthermore, Duhl does not teach including instructions in a kit. While it is noted that the written material in the instructions is not considered to be within the statutory classes and does not carry patentable weight (see MPEP 706.03(a)), the inclusion of instructions in kits was conventional in the art at the time the invention was made. Specifically, Ahern (page 4) teaches including instructions in the kit wherein the instructions provide information as to how to utilize the reagents present in the kit. Accordingly, it would have been further prima facie obvious to one of ordinary skill in the art at the time the invention was made to have included instructions in the kit in order to have facilitated the use of the nucleic acid of Duhl as a probe.

Using the teachings of Ahern to include the primers and probe of Duhl in a kit with instructions would have allowed one of ordinary skill in the art to generate the kit of the present application, aimed at the accurate detection of SEQ ID NO:1, of the present application. Therefore, combining the teachings of Duhl in view of Ahern would have been obvious at the time the invention was made.

Allowable Subject Matter

Claims 1-4 and 8 are free of the prior art and are allowed.

Any inquiry concerning this communication or earlier communication from the examiner should be directed to Sally Sakelaris whose telephone number is (703) 306-0284. The examiner can normally be reached on Monday-Friday from 8:00AM-5:00PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W.Gary Jones, can be reached on (703)308-1152. The fax number for the Technology Center is (703)305-3014 or (703)305-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to Chantai Dessau whose telephone number is (703)605-1237.

Sally Sakelaris

Sally Sakelaris
8/22/02

Carla J. Myers
CARLA J. MYERS
PRIMARY EXAMINER